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REMARKS

In response to the assertion by the examiner that "the structure defined in claim 10 can be used in a materially different process such as suctioning the mouth or a wound in the body." No Sir, it cannot. The said structure defined in claim 10 is beveled at the tip and cannot be used for "a wound on the body" The examiner did not define a wound on the body. Many wounds on the body have small delicate structures; nerves, tendons, micro-arterial and venous structures and connective tissues which would be destroyed by our orotracheal suction to be applied to them. A suctioned intended for use in the oropharynx and trachea cannot be applied to any wound on the body. Suctioning a surgical or traumatic wound on the body, given the size and the particular structures involved, is a completely different enterprise requiring specific suctioning catheters and equipment which are protected by different patents even though they are providing an apparatus which suctions.

For exactly the same reason, there are multiple inventions which are inherently the same device, but used for very different applications even though they have the same basic structure. A Foley catheter is basically a catheter with a balloon. A Swanz-Ganz is basically a catheter with a balloon. A Fogarty catheter is basically

Serial Number 10604469

11

another catheter with a balloon. The Foley is used to drain the bladder. A Swan-Ganz is used to measure pulmonary capillary wedge pressure and cardiac output and the Fogarty catheter is used to remove arterial and venous obstructions.

Per the examiner's logic, one with ordinary skill in the art could easily come up with the Swan Ganz and the Fogarty Catheter since they are the same structure and device as the Foley; flexible catheters with inflatable balloons. The inventor is willing to accept that his invention is not patentable under 35 U.S.C. 103(a) if the examiner can invalidate the patents of the Swanz-Ganz and Fogarty catheters which are the same devices used in different organ systems. The Swan-Ganz catheter and Fogarty are both used in the arteriovenous system. How more obvious and similar can these systems be, yet somehow they achieved patent protection. It has been determined already that one with ordinary skill in the art could not have come with these catheters in light of the Foley catheter.

In this case, the examiner has rejected claims 10,13,14 16-17 as unpatenable over Pell(U.S. Pat. No.4,850,348). et al, in review of Wood (GB)2,220,357 and Joseph (US Pat no 5819723) He has cited three patents that are unrelated to each other and to the the applicant's device. Pell as mentioned before has no function to suction the oropharynx or trachea and as previously presented has no design to capture debris into a receptacle. It is a tube used for endotracheal intubation for use with a ventilator and as a positioning device in the mouth. It has no structure or mechanical design to allow for any suction Someone with ordinary skill in the art cannot think of using this device for any other purpose or they

Serial Number 10604469

12

would have seriously less than even ordinary skill or better stated no skill or dangerous skill in the art. Somehow as the examiner states that one with ordinary skill in the art could conceive of the the applicant's invention in light of Wood's invention and that of Pell et al is so stupid it defies reason. Someone with ordinary skill in this art could in no way come up with the applicant's invention from two unrelated invention.

The device from Joseph as mentioned ad nauseum previously functions to remove a few if that milliliters of tracheal secretions to improve tracheal hygiene in intubated patients. It is desgined to irrigate the area of the proximal trachea only to remove excessive accumulation of fluid in the proximal trachea only. It has no designed apparatus to allow for suctioning and more importantly it is not designed for any removal of debris from the distal trachea or the oropharynx. Someone with ordinary skill cannot in any conceivable way look at the this device "in light" of Pell and Wood and somehow clearly develop a functional device to clear the oropharynx, proximal trachea and distal trachea.

The device from GB by Wood does not have patent protection in this country and how can a person with "ordinary skill" in the art could how link these devices together defies reasonable thinking and is ridiculous. Especially when other devices as mentioned, the Fogarty catheter and Swan-Ganz which are all the same catheters with balloons, essentially the same devices, have each achieved patent protection.

He states that one with ordinary skill in the art could of somehow come up with the

Serial Number 10604469

13

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applicant's invention having known about these other inventions. It has to be said that this is nonsense.

Woods invention is useless in this art. It serves as a inoperable wound suction. Again as previously mentioned ; a wound suction is irrelevant to this art since the tissue and underlying organ system are so different. Someone cannot look at this poor invention by Wood which is not even patented in the US, and apply this suction idea in a different organ system to the field of suctioning the lungs and oropharynx.

What knowledge or training to the examiners have to judge what ordinary skill in this art even is? I present why I understand what ordinary and extraordinary skill in this art is.

I graduated at the top of my medical school class from a United States medical school. I was selected to the medical honor society. I scored a 99% on my US medical licensing exam, one of the most difficult professional licensing exams in the world. I served as the chief of my residency. I practice this art every day of my life a I have studied this art at the highest level through 15 yrs of graduate medical training and experience in some of the top hospitals in the world and can estimate what ordinary skill in this art as well as extraordinary skill. I have studied the patent law for 5 years now of trying this case and find the examiner logic invalid with the poor examples mentioned above. The patent review process is broken. As my patent attorney and many others have said, the goal is for the examiner to prolong this as long as possible, almost always issuing a final rejection and charging another fee. The examiner ,Ted Stigell, also sent me a request for changes to the drawings after I had sent him the changes 3 months prior. The process is

Serial Number 10604469

14

already frustrating and these lapses make it more so. Lest he forget, I documented in an email to him which is saved and to Frederick Schmidt, the supervisor of the entire unit and my attorneys. I called Nick Luchhesi, but he does not respond by phone calls, ever, which has been mentioned to Mr. Schmidt.

This device could save many citizens here and soldiers abroad dying needlessly from acute aspiration and lung injury. I could get it produced if this nonsense at the patent office would stop. I have to send a certified communications as well to John Dudas, Frederick Schmidt, John Love and my neighbor Senator Obama regarding these serious problems with this patent examination process. If these people do not have the skill and knowledge to examine medical devices then they should be removed. The remainder of the remarks still are valid.

Claims 10, 13, 14, and 16-29 are now pending in the application. Claims 18-29 have been withdrawn from consideration. Claims 11, 12, and 15 have been cancelled and the subject matter has been incorporated into Claim 10. Claim 10 as amended now recites that the reservoir includes an entry compartment and a second compartment, that the compartments are separated by a grid, and that the catheter has a diameter of from about 0.5 Fr to about 15 Fr. No new matter has been added. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments and remarks contained herein.

RESTRICTION UNDER 37 C.F.R. 1.142(B)

Serial Number 10604469

15

Applicant respectfully traverses the restriction under 37 C.F.R. 1.142(b) whereby the Examiner withdrew Claims 18-29 from consideration. Claims 18-29 have a sufficient connection to Claims 10-17 such that the restriction is improper. Claims 18-29 are connected to Claim 1 by at least one of the design of the orotracheal suction system, the operation of the orotracheal suction system, and the effect of use of use of the orotracheal suction system. MPEP §802.01(11). Specifically, Claim 18 incorporates the design of the orotracheal suction system of Claim 1, and in turn the system of Claim 1 is required for operation of the method of Claim 18. Further, there is no additional burden placed on the Examiner in examining the related claims together because the apparatus and methods are so related that no extraneous searching or analysis would be required. Accordingly, Applicant asserts that the restriction is improper and requests that Claims 18-29 be considered with Claims 10-17.

REJECTION UNDER 35 U.S.C. § 102

Claims 10, 14, and 16 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Pell et al. (U.S. Pat. No. 4,850,348). This rejection is respectfully traversed.

Serial Number 10604469

16

Pell et al. disclose an endotracheal apparatus made of a material that bends through substantially 90 degrees without the wall collapsing or kinking due to a special tube material formed of silicone, a silica filler, and platinum salts. Column 2, line 62 through Column 3, line 11. The Pell et al. apparatus is disclosed as being adapted to be connected to a ventilator or oxygen source and/or a suction device. Column 3, lines 40-43 and Column 5, lines 27-33.

The focus of the Pell et al. disclosure is the bendable and non-collapsible material, and Pell et al. provide no disclosure on the specifics of the reservoir being



formed as a multi-compartment chamber having a grid separating the entry and second compartments. The Office Action asserts, however, that Pell et al. disclose "a reservoir (the suction source, column 5, line 33) operable to connect to the extension tubing... wherein the reservoir comprises an entry compartment and a second compartment as all reservoirs do..." Office Action at page 5. Applicant is unsure of the foundation of the Office's assertion that "the reservoir comprises an entry compartment and a second compartment as all reservoirs do." Office Action at page 5, emphasis added. As Pell et al. do not disclose any details for the reservoir or for the separating grid, Pell et al. do not disclose each and every element of Applicant's claimed invention as amended, and the §102 rejection is improper. Reconsideration and removal of the §102 rejection of the claims are respectfully requested.

Claims 10, 13-14, and 16-17 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Joseph (U.S. Pat. No. 5,819,723). This rejection is respectfully traversed.

Joseph discloses a tracheal tube system and related methods for preventing the spread of infected secretions into the distal trachea where the tracheal tube system blocks the infected secretions and delivers an irrigating liquid to the area via an irrigation channel near the exterior surface of the tracheal tube. Column 4, lines 34-53 and Column 7, lines 46-62. Joseph discloses a canister 402 for removing aspirated fluids and a suction regulator, where the suction source is typically wall suction.

Serial Number 10604469

18



Column 8, lines 13-28.

Joseph does not disclose any additional information on the canister 402 and provides no disclosure on the specifics of the reservoir being formed as a multi

Serial Number 10604469

19

compartment chamber having a grid separating the entry and second compartments.

The Office Action indicates that Joseph discloses "a reservoir (402) operable to connect to the extension tubing... wherein the reservoir comprises an entry compartment and a second compartment as all reservoirs do, wherein the reservoir has a grid and a removable disc..." Office Action at pages 5-6. Again, Applicant is unsure of the foundation of the Office's assertion that "the reservoir comprises an entry compartment and a second compartment as all reservoirs do." Office Action at page 5, emphasis added. As Joseph does not disclose any details for the reservoir, Joseph does not disclose each and every element of Applicant's claimed invention as amended, and the §102 rejection is improper. Reconsideration and removal of the §102 rejection of the claims is respectfully requested.

#### CONCLUSION

Applicant submits that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. Thanks so much and have a nice day.

Serial Number 10604469

20

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Serial Number 10604469

21